UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
CASE NO.: _____

ELI LILLY AND COMPANY,

Plaintiff,

v.

RXCOMPOUNDSTORE.COM, LLC

Defendant.

COMPLAINT

Plaintiff Eli Lilly and Company ("Plaintiff" or "Lilly"), brings this action against Defendant Rxcompoundstore.com, LLC ("Defendant" or "Rx") and alleges the following:

I. NATURE OF THE ACTION

1. Lilly brings this action to stop Defendant from unlawfully manufacturing and selling unapproved new drugs. Florida state laws require drug manufacturers to demonstrate their drugs are safe and effective in order to obtain regulatory approval to market them. Defendant violates these laws by marketing and selling unapproved new drugs throughout Florida and fourteen other states (Delaware, Pennsylvania, New York, Arizona, New Jersey, Wisconsin, Minnesota, Rhode Island, Utah, Georgia, Nevada, Massachusetts, Missouri and Colorado).

A. Florida Laws Against Unlawful and Unfair Business and Trade Practices

2. Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA") "protect[s] the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.202(2). FDUTPA further forbids Defendant from violating "[a]ny

law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." Fla. Stat. § 501.203(3)(c).

B. Florida Laws Prohibiting the Sale of Unapproved Drugs

3. Florida regulates the manufacture and sale of prescription drugs under the state's Drug and Cosmetic Act. As relevant here, the Florida Drug and Cosmetic Act specifies that no person may "sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the [Federal Food, Drug, and Cosmetic Act] or otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce." Fla. Stat. § 499.023. Florida's drug-approval provision is designed to ensure that when Floridians are treated with prescription drugs, they can rest assured that the products are safe and effective for their intended uses.

4. Defendant disregards these and other state laws respecting the distribution of unapproved drugs. Rather than invest the time and resources necessary to research, develop, and test their products in order to ensure that they are safe and effective and to obtain regulatory approval to market them, Defendant is simply creating, marketing, selling, and distributing unapproved new drugs for unapproved uses throughout Florida and fourteen other states (Delaware, Pennsylvania, New York, Arizona, New Jersey, Wisconsin, Minnesota, Rhode Island, Utah, Georgia, Nevada, Massachusetts, Missouri and Colorado).

D. The Importance of Drug Approval and the Purpose of this Action

5. Defendant's business model is unlawful. Defendant is engaged in unlawful and unfair business and trade practices because Defendant manufactures and dispenses drugs in

violation of the Florida Drug and Cosmetic Act, which prohibits the sale of drugs not approved by FDA.

6. Testing new drugs and obtaining the legally required regulatory approval to sell them is time-consuming and very costly. Ignoring drug-approval requirements provides Defendant an unfair competitive advantage over law-abiding pharmaceutical manufacturers like Lilly. Worse, it puts patients at risk by exposing them to drugs that have not been shown to be safe or effective.

7. Federal and state law require approval for new drugs for good reason. Drug approval is evidence-based, and it is essential to ensure the quality, safety, and effectiveness of new drugs. When companies circumvent the drug-approval process, safety and efficacy are, at best, unknown. The danger is not merely theoretical, as manufacturing and distribution of unapproved new drugs of unknown quality has endangered or adversely impacted public health. For example, in 2012, nearly 800 patients in 20 states were diagnosed with a fungal infection after receiving injections of an unapproved preservative-free methylprednisolone acetate drug manufactured in Massachusetts. Of those 753 patients, the U.S. Centers for Disease Control and Prevention reported that 64 patients in nine states died, though other sources report the death toll as exceeding 100 victims. Other adverse events related to the sale of unapproved and unsafe drugs have occurred in the years following 2012.

8. Lilly brings this action under FDUTPA to stop Defendant from unlawfully manufacturing, marketing, selling, and distributing unapproved new drugs. Lilly seeks a declaration that Defendant's business practices violate FDUTPA by manufacturing, distributing, and selling unapproved new drugs and an injunction prohibiting Defendant from committing such violations. Fla. Stat. §§ 499.023, 501.211(1).

9. Lilly also seeks attorney's fees and court costs. *See* Fla. Stat. § 501.211(2).

THE PARTIES

10. Lilly is a corporation organized and existing under the laws of the State of Indiana, with a principal place of business in Indiana.

11. Lilly markets and sells Mounajro®, which contains the active pharmaceutical ingredient tirzepatide. Mounjaro® is the only FDA-approved drug containing tirzepatide as its active pharmaceutical ingredient.

12. Plaintiff sells Mounjaro® to medical facilities and customers across the United States, including in Florida.

13. Plaintiff has invested significant time and resources to research, develop, manufacture, and test Mounjaro® in order to obtain regulatory approval from FDA to market it as a treatment for type 2 diabetes mellitus.

14. Defendant is a limited liability company organized and existing under the laws of Florida, with its principal place of business at 8950 SW 74th CT, Suite 101, Miami, FL 33156.

15. Upon information and belief, all members of Defendant are citizens of Florida. The Florida Secretary of State's records list Mario Guillermo Tabraue as Defendant's manager. According to an Accurint® background report, Mario Tabraue resides in Miami-Dade County, Florida. The Florida Secretary of State's records do not identify any current members of Defendant. However, they identify a former member/manger, Ruth Yankiver, and reflect that she resigned in 2020. A report from D&B Hoovers® identifies Earth Science Tech, Inc., a Florida corporation, as Defendant's parent. The Florida Secretary of State's records indicate that Earth Science Tech, Inc.'s principal address is 8000 NW 31st St, Suite 19, Doral FL 33122. They also indicate that Mario Tabraue is Earth Science Tech, Inc.'s President, Director.

16. Defendant markets itself as shipping products throughout Florida and fourteen other states (Delaware, Pennsylvania, New York, Arizona, New Jersey, Wisconsin, Minnesota, Rhode Island, Utah, Georgia, Nevada, Massachusetts, Missouri and Colorado). Defendant sells its unapproved drug products in fifteen states, including in this judicial District. The unapproved drug products Defendant offers for sale and ships throughout fifteen states include unapproved drugs, some of which, Defendant represents, contain tirzepatide.

II. JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction under 28 U.S.C. § 1332. The parties are citizens of different States (¶¶ 10–16, *supra*), and the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

18. This Court has personal jurisdiction over Defendant. Defendant sells its unapproved drugs from this District and ships them from this District across fifteen states (Delaware, Florida, Pennsylvania, New York, Arizona, New Jersey, Wisconsin, Minnesota, Rhode Island, Utah, Georgia, Nevada, Massachusetts, Missouri and Colorado). Plaintiff's claims arise out of or relate to Defendant's activities in this District.

19. Venue in this District is proper under 28 U.S.C. § 1391(b).

III. FACTUAL ALLEGATIONS

A. Plaintiff Sells the only Tirzepatide Drug Approved by FDA for Sale in the United States

20. Plaintiff sells Mounjaro® pursuant to New Drug Application #NDA 215866, which FDA approved on May 13, 2022, as a treatment for type 2 diabetes.

21. Plaintiff is the only supplier of FDA-approved tirzepatide drugs in the United States.

B. Defendant's Activities Violate Florida Laws Against Selling Unapproved Drugs

1. Florida laws require Drug Approval

22. Defendant's manufacturing, marketing, sale, and distribution of unapproved new drugs is unlawful.

23. Under the laws of Florida, a new drug may not be introduced or delivered for introduction into interstate or intrastate commerce unless an application approved under section 505 of the federal act is in effect for the drug. *See* Fla. Stat. § 499.023.

24. Florida's Drug and Cosmetic Act provides that no person may "sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce." Fla. Stat. § 499.023.

25. Defendant does not have an approved New Drug Application or Abbreviated New Drug Application for any drug product purporting to contain tirzepatide.

26. Defendant is violating FDUTPA because (i) it is selling its unapproved tirzepatide drugs nationwide, including from Florida to customers in Florida (and throughout the United States); and (ii) it has not obtained the approval of any relevant regulatory authority to introduce into any state, or into interstate commerce generally, the unapproved drug purporting to contain tirzepatide that it manufactures, markets, sells, and distributes.

C. Defendant's business and trade practices jeopardize public health

27. Defendant's unfair competition jeopardizes public health. FDA has stated that unapproved drugs pose a higher risk to patients than FDA-approved drugs because they have not undergone FDA premarket review for safety, effectiveness, and quality. FDA's *Guidance for Industry, Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic*

Act at 4 (December 2016). "Compounded drugs are not FDA-approved, and the agency does not verify the safety or effectiveness of compounded drugs." FDA's *Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss* (May 31, 2023). "Purchasing medicine online from unregulated, unlicensed sources can expose patients to potentially unsafe products that have not undergone appropriate evaluation or approval, or do not meet quality standards." *Id.*

28. Defendant sells its unapproved drugs, including its purported tirzepatide drug, without any assurances of the drug's identity, strength, quality, and purity.

D. Plaintiff has been Injured by Defendant's Unlawful and Unfair Competition

29. Defendant's actions have injured Plaintiff. Plaintiff is the only supplier in the United States of FDA-approved tirzepatide drugs.

30. Defendant sells its unapproved drugs purporting to contain tirzepatide to customers in Florida and fourteen other states (Delaware, Pennsylvania, New York, Arizona, New Jersey, Wisconsin, Minnesota, Rhode Island, Utah, Georgia, Nevada, Massachusetts, Missouri and Colorado). Some sales made by Defendant in each of these states would have been made by Plaintiff, but for Defendant's unlawful and unfair competition, and Plaintiff has suffered financial harm as a direct result of Defendant's unlawful and unfair competition.

31. As a result of Defendant's unlawful and unfair competition as described above, Plaintiff has suffered financial harm. Defendant's unlawful sales of its purported tirzepatide drug are also injuring the reputation of Plaintiff because of Defendant's business and trade practices that jeopardize public health.

IV. CAUSES OF ACTION

COUNT ONE

(Violation of Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.201, *et seq)*

32. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1-31, above, as if fully stated herein.

33. FDUTPA makes unlawful "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.204.

34. FDUTPA also creates a cause of action for "anyone aggrieved" by a violation of FDUTPA to bring an action against "a person who has violated, is violating, or is otherwise likely to violate" the Act. Fla. Stat. § 501.211.

35. Plaintiff is "aggrieved" under FDUTPA.

36. Defendant is a "person" who has violated and is violating FDUTPA.

37. Defendant engages in unfair, unconscionable, and deceptive conduct in "trade" and "commerce" in violation of FDUTPA when it unlawfully manufactures and sells unapproved drugs in Florida, including its unapproved new drugs purporting to contain tirzepatide.

38. Given that Defendant's drugs are unapproved (and therefore pose potential harm to consumers), Defendant's manufacture and sale of its drugs is a practice that is immoral, unethical, oppressive, unscrupulous, and/or substantially injurious to physicians, medical facilities and patients alike.

39. The practices described herein also offend established public policy regarding the protection of consumers against companies, like Defendant, that engage in unfair methods of

competition. Defendant's conduct has caused financial harm to Plaintiff that is not outweighed by countervailing benefits to any consumers or competition.

40. Consumers in Florida who unwittingly purchased Defendant's illegal new drugs purporting to contain tirzepatide were deceived about the lawfulness of Defendant's product and and deprived of the benefit of their bargain.

41. Defendant's business acts and practices are also unfair because they have caused harm and injury-in-fact to Lilly for which Defendant has no justification other than to increase, beyond what Defendant would have otherwise realized, its market share and revenue from the sale of unapproved drugs.

42. Defendant has further violated FDUTPA by violating a "statute . . . which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." Fla. Stat. 501.203(3)(c). Here, Defendant violated Florida's Drug and Cosmetic Act which proscribes certain unconscionable acts and practices.

43. In addition to injury in excess of $75,000, Plaintiff is entitled to declaratory and injunctive relief, the value of which exceeds $75,000, as well as reasonable attorney's fees and costs pursuant to Fla. Stat. §§ 501.2105, 501.211.

V. CONCLUSION AND PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor:

1. A permanent injunction enjoining Defendant from continuing the unlawful and unfair business practices alleged in this complaint, which injunction has a value to Plaintiff in excess of $75,000;

2. A judgment that Defendant violated FDUTPA;

3. Declaratory relief;

4. Attorney's fees and costs incurred in this action; and

5. Any further relief the Court may deem just and proper.

Dated: September 19, 2023

Respectfully submitted,

KING & SPALDING LLP

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